

## REMARKS

### I. Amendment

In this response, claims 52 and 53 have been cancelled.

No amendment of inventorship is necessitated by this amendment.

### II. Request for a Clarification of the Status of a Previous Rejection

Applicants wish to remind the Examiner that the Final Office Action dated June 15, 2004 contained a rejection under 35 U.S.C. Sec. 102(e) over Lundberg (U.S. Patent No. 6,132,770). Yet the Examiner did not indicate either that the rejection had been overcome or was still standing in the Office Action mailed March 21, 2005. Applicants respectfully request that the Examiner state for the record whether or not the previous rejection has been overcome.

### III. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Lundberg

Claims 1-3, 5, 7, 9, 11-19, 21-24, 29, 31 and 50-53 stand rejected under 35 U.S.C. Sec. 103(a) as allegedly unpatentable over Lundberg (U.S. Patent No. 6,132,770). Applicants respectfully traverse the rejection.

The Examiner is still mistaken in thinking that since the cited reference teaches that an effervescent tablet has a disintegrating time of about 55 seconds, that the aspects of the invention presently claimed are obvious.

As Applicants have stressed before, the time referred to in the cited art (i.e. effervescence time) was measured by putting a tablet in a basket of metal wiring and then immersing the basket in 300 ml of water (Example 1) or in 150 ml of water (Examples 3, 4, 5 and 6). The dissolution times disclosed in the cited art were therefore obtained under vastly different conditions than Applicants' recited buccal dissolution times, measured as the time for healthy adults to complete disintegration by buccal saliva.

Those skilled in the art already understand that while the orally disintegrable tablet of the present invention is capable of being dissolved with the patient's saliva without additional water, the effervescent tablet of the cited art must be dissolved or dispersed in large amount of water before administration. The two methods of disintegration are non-analogous.

Applicants previously submitted a Declaration which proved this point, the Shimizu Declaration. On pages 4 and 5 of that Declaration, Applicants showed that test patients could not even keep effervescent tablets in their mouths long enough to achieve dissolution, as after one minute, it was too uncomfortable for them to keep the tablets in their mouth. This is so because effervescent tablets are not designed to dissolve orally. They are not analogous art to the presently claimed preparations.

The Examiner's comments on page 6 of the Office Action give two reasons for discounting the Shimizu Declaration. Applicants do not find her reasons to be logical. As to the first reason given, there is no need for a side-by-side comparison. By way of analogy, one may think of running two racecars side-by-side to see which is faster. But if one of the racecars is inoperable due to engine failure, there is no need for a race. Similarly, Applicants have already shown that effervescent tablets are inoperable for oral administration. There is no need for a side-by-side test because Applicants have already proven that the art effervescent tablets are not even tolerable as oral treatments.

As to the second reason given, it is irrelevant that "the amount of CO<sub>2</sub> evolved in a patient's mouth is not what is being claimed". The tests in the Declaration showed that the effervescent tablets gave off so much CO<sub>2</sub> that patients would not be able to take them orally. Thinking back to the racecar analogy, the amount of CO<sub>2</sub> evolved is merely proof of the broken engine (inoperability). Since Applicants have recited buccal dissolution times in each of the independent claims, they believe that the evidence in the Shimizu Declaration is commensurate in scope with the pending claims.

So the Applicants have argued that the cited art is non-analogous, and reinforced that argument by presenting test data in the form of a Declaration.

Since the Examiner has not been able to understand the differences between the dissolution of effervescent tablets in water and Applicants' claimed buccal dissolution in the form of presented arguments, supplemental supportive literature references and a Declaration, Applicants now provide a conceptual idea for the Examiner to consider in order to illustrate the

differences between the dissolution times of the presently claimed invention and dissolution times of the effervescent tablets, as in the cited art.

Television has been used to advertise the effervescent tablets known as ALKA-SELTZER. Perhaps the Examiner recalls the ads, wherein the phrase “plop, plop, fizz, fizz, oh what a relief it is” was sung. If the Examiner does not recall it, the advertisement can be heard by clicking on the word “jingle” found in the descriptive text at [www.snopes.com/business/genius/alka-seltzer.asp](http://www.snopes.com/business/genius/alka-seltzer.asp). The “plop, plop” represented the sound of the tablet dropping into a glass of water, and the “fizz, fizz” represented the sound of effervescence begun as dissolution started taking place in the glass. This catchy tune educated the general public as to the administration method for taking effervescent tablets. Such a tablet does not go into the mouth for dissolution, but into a glass of water for dissolution.

Were the effervescent tablets efficiently or comfortably dissolvable in the mouth, “plop, plop, fizz, fizz” would be unnecessary. Dissolving an effervescent tablet in a large amount of water is vastly different than dissolving an oral tablet in the mouth with saliva, where there is a paucity of water. That is why Applicants persist in arguing that the cited art is non-analogous.

Moreover, Applicants’ previous Declarations have proven that human patients cannot tolerate “fizz, fizz” when it occurs in their mouths rather than in a glass.

Applicants do not believe that the aspects of their invention as set forth in independent claim 1 is rendered obvious by the cited art for the reasons provided above. Claims 2, 3, 5, 7, 9, 11-19, 21-24, 29, 31, 50 and 51 depend upon claim 1. Claims 52 and 53 have been cancelled. Applicants submit that the more specific dependent claims are also not rendered obvious for the same reasons.

Therefore Applicants respectfully request withdrawal of the rejection under 35 U.S.C. Sec. 103(a) over Lundberg.

#### **IV. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Lundberg in view of Watanabe *et al.***

Claims 1-3, 5, 7, 9, 11-19, 21-24, 29, 31 and 50-53 have been rejected as being unpatentable over Lundberg, (U.S. Patent No. 6,132,770), in view of Watanabe *et al.*, (Biol. Pharm. Bull. 1995 article). Applicants respectfully traverse the rejection.

As an initial matter, Applicants note that the Examiner's comments on page 4 of the Office Action are contradicted by her comments on page 3 of the Office Action. The Examiner first says that Lundberg also teaches tablets having disintegrating time of about 55 seconds on page 3, while on page 4, the Examiner states "Lundberg is silent as to the teaching of the disintegration time in one minute or less".

Applicants have discussed Lundberg exhaustively in Sec. III above. Applicants hereby incorporate the arguments made in that section to this section.

The Watanabe *et al.* article is clearly directed to tablets which can be dissolved orally with only saliva. As Applicants have explained in detail, the Lundberg reference is not directed to such tablets. Therefore, there would be no reason to combine the teachings of references directed to two different methods of tablet administration. Thus the combined teaching of the two references does not render the aspects of the present invention as set forth in the pending claims obvious, as those skilled in the art would not look to a reference directed to effervescent tablets when designing a tablet to be dissolved in the mouth with saliva.

Applicants do not believe that the aspects of their invention as set forth in independent claim 1 is rendered obvious by the combined teachings of the cited art for the reasons provided above. Claims 2, 3, 5, 7, 9, 11-19, 21-24, 29, 31, 50 and 51 depend upon claim 1. Claims 52 and 53 have been cancelled. Applicants submit that the more specific dependent claims are also not rendered obvious for the same reasons.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 103(a) over Lundberg *et al.* in view of Watanabe *et al.*

## **V. Discussion of the Additionally Cited Art**

Applicants wish to thank the Examiner for bringing the cited art of Ueda *et al.*, Gergely *et al.* and Misra *et al.* to their attention. Applicants have carefully reviewed these references and do not believe that they detract from the patentability of the subject invention.

However, the Examiner has also listed Mizumoto *et al.*, Lattanzi *et al.* and Makino *et al.* at the bottom of page 6 of the Office Action. Since these references are not included on the Examiner's form PTO-892, Applicants do not know what the references are. Clarification is requested.

## VI. Conclusion

Reconsideration and allowance of the pending claims is requested in light of the amendment and arguments provided above. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, she is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

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(847) 383-3391  
(847) 383-3372

Elaine M Ramesh  
Elaine M. Ramesh, Ph.D., Reg. No. 43,032  
Mark Chao, Ph.D., Reg. No. 37,293  
Attorney for Applicants  
Customer No. 23115

Takeda Pharmaceuticals North America, Inc.  
Intellectual Property Department  
475 Half Day Road  
Lincolnshire, IL 60069 USA

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